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INSIDE THIS ISSUE

STATE-OF-THE-ART REVIEW

Drug Delivering Technology for Endovascular Management of Infrainguinal Peripheral Artery Disease

827

Karan Sarode, David A. Spelber, Deepak L. Bhatt, Atif Mohammad, Anand Prasad, Emmanouil S. Brilakis, Subhash Banerjee

Endovascular management of peripheral artery disease has historically had high restenosis rates leading to repeat interventions. The innovation of locally administered, antiproliferative drug delivering technology is an attempt to overcome these shortcomings. This review highlights the results of numerous completed and ongoing clinical trials examining the efficacy and indications of use of these novel devices. Additionally, it explores combination therapies and promising new treatment modalities for the management of peripheral artery disease, along with the challenges and safety concerns that may have contributed to the potential delay in the U.S. Food and Drug Administration approval of these devices.

CLINICAL RESEARCH

CORONARY

Three-Year Outcomes After Revascularization With Everolimus- and Sirolimus-Eluting Stents From the SORT OUT IV Trial

840

Lisette Okkels Jensen, Per Thayssen, Michael Maeng, Evald Høj Christiansen, Jan Ravkilde, Knud Nørregaard Hansen, Anne Kaltoft, Hans Henrik Tilsted, Morten Madsen, Jens Flensted Lassen, for the Scandinavian Organization for Randomized Trials With Clinical Outcome SORT OUT IV Investigators

In the SORT OUT IV TRIAL (SORT OUT), the outcomes at 3 years were assessed with focus on very late definite stent thrombosis. The composite primary endpoint occurred in 9.8% of the everolimus-eluting stent (EES) group and in 11.1% of the sirolimus-eluting stent group (hazard ratio [HR]: 0.89, 95% confidence interval [CI]: 0.70 to 1.12). The rate of definite stent thrombosis was lower in the EES group (0.2% vs. 1.4%, HR: 0.15, 95% CI: 0.04 to 0.50), which was largely attributable to a lower risk of very late definite stent thrombosis: 0.1% versus 0.8% (HR: 0.09, 95% CI: 0.01 to 0.70).

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**Randomized Comparison of Everolimus-Eluting Stents and Sirolimus-Eluting Stents in Patients With ST Elevation Myocardial Infarction: RACES-MI Trial****849**

Emilio Di Lorenzo, Rosario Sauro, Attilio Varricchio, Michele Capasso, Tonino Lanzillo, Fiore Manganelli, Giannignazio Carbone, Francesca Lanni, Maria Rosaria Pagliuca, Giovanni Stanco, Giuseppe Rosato, Harry Suryapranata, Giuseppe De Luca

No data have been reported so far on the long-term benefits and safety of the new generation drug-eluting stent(s) in ST-segment elevation myocardial infarction (STEMI). Therefore, the authors compared everolimus-eluting stent(s) (EES) with sirolimus-eluting stent(s) (SES) in 500 STEMI patients undergoing primary angioplasty. At 3-year follow-up, no significant difference was observed between EES and SES in major adverse cardiac events ($p = 0.17$), Cardiac death ($p = 0.53$), recurrent MI ($p = 0.13$) and target vessel revascularization ($p = 0.99$). However, EES was associated with a significant reduction in stent thrombosis ($p = 0.035$). This study shows that among STEMI patients, EES, as compared to SES, is associated with a significant reduction in stent thrombosis.

A Registry-Based Randomized Trial Comparing Radial and Femoral Approaches in Women Undergoing Percutaneous Coronary Intervention: The SAFE-PCI for Women (Study of Access Site for Enhancement of PCI for Women) Trial**857**

Sunil V. Rao, Connie N. Hess, Britt Barham, Laura H. Aberle, Kevin J. Anstrom, Tejan B. Patel, Jesse P. Jorgensen, Ernest L. Mazzaferri Jr., Sanjit S. Jolly, Alice Jacobs, L. Kristin Newby, C. Michael Gibson, David F. Kong, Roxana Mehran, Ron Waksman, Ian C. Gilchrist, Brian J. McCourt, John C. Messenger, Eric D. Peterson, Robert A. Harrington, Mitchell W. Krucoff

Women are at increased risk of bleeding and vascular complications after percutaneous coronary intervention (PCI). Rao and colleagues conducted a registry-based randomized trial to determine the efficacy and feasibility of radial access in women. The trial was stopped early for a lower than expected event rate. There was no significant difference in the primary efficacy endpoint between radial and femoral access in women undergoing PCI, but in women undergoing cardiac catheterization or PCI, radial access significantly reduced bleeding and vascular complications. Access site crossover was significantly higher in women assigned to radial access, but more women preferred radial access.

**SEE ADDITIONAL CONTENT ONLINE****Intravascular Ultrasound-Derived Minimal Lumen Area Criteria for Functionally Significant Left Main Coronary Artery Stenosis****868**

Seung-Jung Park, Jung-Min Ahn, Soo-Jin Kang, Sung-Han Yoon, Bon-Kwon Koo, Jong-Young Lee, Won-Jang Kim, Duk-Woo Park, Seung-Whan Lee, Young-Hak Kim, Cheol Whan Lee, Seong-Wook Park

Evaluation of significant left main coronary artery (LMCA) stenosis remains challenging. Therefore, the authors examined the usefulness of the intravascular ultrasound (IVUS) minimal lumen area (MLA) for the functional significance of LMCA stenosis using fractional flow reserve as the standard. They found that IVUS MLA was an independent factor of functionally significant stenosis with an optimal cutoff value of 4.5 mm^2 . In conclusion, in patients with isolated ostial and shaft intermediate LMCA stenosis, an IVUS-derived MLA of $\leq 4.5 \text{ mm}^2$ is a useful index of a fractional flow reserve of ≤ 0.80 .

**STRUCTURAL****Survival of Transcatheter Mitral Valve Repair Compared With Surgical and Conservative Treatment in High-Surgical-Risk Patients****875**

Martin J. Swaans, Annelies L. M. Bakker, Arash Alipour, Martijn C. Post, Johannes C. Kelder, Thom L. de Kroon, Frank D. Eefting, Benno J. W. M. Rensing, Jan A. S. Van der Heyden

Up to 50% of patients with symptomatic severe mitral valve (MV) regurgitation (MR) are denied for surgery due to high perioperative risk. Transcatheter MV repair might be an alternative. Swaans and colleagues compared survival between transcatheter MV repair using the MitraClip system (Abbott Vascular, Santa Clara, California) ($n = 139$), MV surgery ($n = 53$), and conservative treatment ($n = 59$) in high-surgical-risk patients with symptomatic severe MR. The authors show that despite a higher logistic European System for Cardiac Operative Risk Evaluation, high-surgical-risk patients with severe symptomatic MR treated with transcatheter MV repair show similar survival rates compared with surgically treated patients, with both displaying survival benefit compared with conservative treatment.

■ EDITORIAL COMMENT**The Saga Continues: Does Mitral Valve Repair Improve Survival in Secondary Mitral Regurgitation?****882**

Robert O. Bonow

Quantity and Location of Aortic Valve Complex Calcification Predicts Severity and Location of Paravalvular Regurgitation and Frequency of Post-Dilation After Balloon-Expandable Transcatheter Aortic Valve Replacement**885**

Omar K. Khalique, Rebecca T. Hahn, Hemal Gada, Tamim M. Nazif, Torsten P. Vahl, Isaac George, Bindu Kalesan, Molly Forster, Mathew B. Williams, Martin B. Leon, Andrew J. Einstein, Todd C. Pulerwitz, Gregory D. N. Pearson, Susheel K. Kodali

Paravalvular regurgitation (PVR) and the need for balloon post-dilation (PD) are important outcomes following transcatheter aortic valve replacement given the associated morbidity and mortality that may occur. Previous literature has been mixed regarding the role of calcification in different locations of the aortic valve complex on PVR and PD. In the current study, Khalique et al. have found that calcification in all regions of the aortic valve complex significantly predicts PVR and PD. Leaflet and anchoring zone calcification are independent predictors of PVR and PD when factoring in relative valve to annulus sizing.

**SEE ADDITIONAL CONTENT ONLINE****■ EDITORIAL COMMENT****Paravalvular Regurgitation and Post-Deployment Balloon Dilation After Transcatheter Aortic Valve Replacement: Can We Predict and Prevent?****895**

Paolo Raggi



Comparison of Transfemoral Transcatheter Aortic Valve Replacement Performed in the Catheterization Laboratory (Minimalist Approach) Versus Hybrid Operating Room (Standard Approach): Outcomes and Cost Analysis **CME**

898

Vasilis Babaliaros, Chandan Devireddy, Stamatios Lerakis, Robert Leonardi, Sebastian A. Iturra, Kreton Mavromatis, Bradley G. Leshnower, Robert A. Guyton, Mihir Kanitkar, Patricia Keegan, Amy Simone, James P. Stewart, Nima Ghasemzadeh, Peter Block, Vinod H. Thourani

As experience with transcatheter aortic valve replacement (TAVR) has increased, some centers have performed transfemoral TAVR in a standard cardiac catheterization laboratory without general anesthesia or transesophageal echocardiography. Babaliaros and colleagues compared the safety, efficacy, and cost of such a minimalist approach to the current standard approach performed in a hybrid operating room. The minimalist approach was associated with equivalent safety and efficacy outcomes compared with the standard approach, with lower costs and shorter length of stay. The authors believe that these results have important implications for the financial viability of U.S. TAVR programs in the future.

Results of the U.S. Food and Drug Administration Continued Access Clinical Trial of the GORE HELEX Septal Occluder for Secundum Atrial Septal Defect

905

Alexander J. Javois, Jonathan J. Rome, Thomas K. Jones, Evan M. Zahn, Craig E. Fleishman, Ricardo H. Pignatelli, Larry A. Latson, for the Gore HELEX Continued Access Study Group

The immediate, 1-, and 5-year follow-up outcomes of the Continued Access clinical trial of the GORE HELEX Septal Occluder (W. L. Gore & Associates, Inc., Flagstaff, Arizona) are reported. The overall clinical success was 96.7%, and major adverse event rate was 3.6%. Wire frame fractures were seen in 11.7% of patients with no clinical symptoms. A trivial, clinically insignificant leak was seen, or could not be ruled out, in 26.6% of patients at the 5-year evaluation, but no clinically significant leaks were seen. No patient experienced an erosion or sudden catastrophic event.

**PERIPHERAL VASCULAR****Predictors of Recurrent Events in Patients With Cryptogenic Stroke and Patent Foramen Ovale Within the CLOSURE I (Evaluation of the STARFlex Septal Closure System in Patients With a Stroke and/or Transient Ischemic Attack Due to Presumed Paradoxical Embolism Through a Patent Foramen Ovale) Trial****913**

Sammy Elmariah, Anthony J. Furlan, Mark Reisman, David Burke, Moshe Vardi, Neil J. Wimmer, Shuqiong Ling, Xiaohua Chen, David M. Kent, Joseph Massaro, Laura Mauri, for the CLOSURE I Investigators

This is a post-hoc analysis aimed at identifying risk factors for the development of recurrent neurologic events in patients with cryptogenic stroke and patent foramen ovale within the CLOSURE I (Evaluation of the STARFlex Septal Closure System in Patients With a Stroke and/or Transient Ischemic Attack Due to Presumed Paradoxical Embolism Through a Patent Foramen Ovale) trial. In 909 patients, the incidence of recurrent events was 5.7% at 2 years. Diabetes, index transient ischemic attack, and the detection of atrial fibrillation after enrollment independently predicted recurrent neurologic events. Recurrent neurologic events were also more frequent in subjects with a lower RoPE (Risk of Paradoxical Embolism Score). These findings suggest an alternative etiology to paradoxical embolism was frequently responsible for recurrent events within the CLOSURE I trial.

■ EDITORIAL COMMENT**The Paradox of Paradoxical Embolism and Recurrent Stroke****921**

Alex Abou-Chebl

Lower Extremity Revascularization Using Directional Atherectomy: 12-Month Prospective Results of the DEFINITIVE LE Study**923**




James F. McKinsey, Thomas Zeller, Krishna J. Rocha-Singh, Michael R. Jaff, Lawrence A. Garcia, on behalf of the DEFINITIVE LE Investigators

The goal of this study was to objectively assess the safety and effectiveness of directional atherectomy (DA) in patients with claudication or critical limb ischemia (CLI). Primary endpoints were 12-month primary patency for claudicants and freedom from major unplanned amputation for CLI subjects. CLI secondary endpoints included 12-month primary patency. In 800 subjects, the 12-month primary patency rate was 78% in claudicants including 77% in the diabetic subgroup versus 78% in the nondiabetic subgroup ($p < 0.001$). The rate of freedom from major unplanned amputation at 12 months in CLI subjects was 95% with a 71% primary patency rate. DA is safe and effective treatment at 12 month for a diverse patient population.

**SEE ADDITIONAL CONTENT ONLINE****■ EDITORIAL COMMENT****The DEFINITIVE LE: Atherectomy's Ability to Leave No Trace or Need for More DEFINITIVE Data?****934**

Andrew J.P. Klein

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